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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,791	08/08/2001	David Hung	12.019011	9920

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,791	HUNG, DAVID	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed March 9, 20041) in response to the Office Action of September 9, 2003 is acknowledged and has been entered. Claims 1, 2, 5-15, 17-20 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a) as being unpatentable over Love et al. (U.S.Pat. No. 6,221,622, IDS) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), Makita et al. (Breast Cancer Research, 1991, IDS), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirology 1997) and Androphy (Ciba Found. Symposium, 1986) **is withdrawn** in view of Applicant's amendments to the claims.

New rejection in view of Applicant's amendment:

Claims 1, 2, 5-15, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evron et al. (Lancet, April 28, 2001) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), Makita et al. (Breast Cancer Research, 1991, IDS), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirology 1997) and Androphy (Ciba Found. Symposium, 1986).

The instant invention is drawn to a method comprising the steps of obtaining fluid and washing fluid from a single breast duct and analyzing the sample for the presence of a viral agent. The viral agent is identified with a viral marker (whole virus, protein or nucleic acid). The invention further comprises treating a patient at risk by administering an antiviral agent. The antiviral agent can be administered through catheter to the breast duct or the agent can be administered systemically.

A recitation of the intended use "identifying a patient at risk of developing breast cancer or pre-cancer" of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The term "identifying a patient at risk of developing breast cancer or pre-cancer" is being viewed as an intended use which confers no further substance to the claim and is given little patentable weight (see In re Pearson, 494 F.2nd 1399, 1403, 181 USPQ 641, 664 (CCPA 1974)).

Evron et al. teaches the use of ductal lavage using a microcatheter to collect epithelial cells from the breast duct and analyzing the samples for atypical and malignant cells. Althopught the reference teaches detection of atypical cells, the reference does not teach analyzing for atypical cells due to the presence of a virus or detecting a viral protein or viral marker.

Sukumar et al. (U.S. Pat. No. 5,763,415) teaches the use of cannulation of the breast duct to introduce an epithelial cell destroying agent/vector into a breast duct at risk of developing solid tumors. The reference does not teach using a virus specific agent. The composition used by the reference destroys epithelial cells, which are the cells that are infected by papillomavirus. The reference acknowledges the advantage of treating a single duct, which will result in the preservation of the remainder of the breast tissue. The reference establishes that at the time the invention was made that it was known in the art to introduce a treatment agent into the breast duct.

Makita et al. (Breast Cancer Research, 1991, IDS) teaches using duct endoscopy to obtain a biopsy sample from a single breast duct, followed by analyzing the sample to see if the contains a viral agent, such as papilloma (table 1). The reference establishes that at the time the invention was made it was known in the art that papillomavirus is present in the epithelial cells of the breast duct.

King et al. (JNCI, 1983, IDS) teaches that fluid obtained from nipple aspirate can be used to assess the presence of a viral agent, papilloma and papilomatosis (see table 5). The reference obtains fluid from multiple ducts and not a single duct. The reference establishes that at the time the invention was made it was known in the art that papillomavirus can be detected in fluid samples obtained from breast ducts. The reference does not teach infusion of the breast duct with antiviral agents after discovering the presence of a viral agent.

Noguchi et al. teach using PCR analysis to determine the presence of papillomavirus in the breast duct. In this reference the samples were obtained from surgical samples and not from fluid extractions of the breast. The reference does teach the correlation between multiple

intraductal papillomavirus lesions and pre-cancerous lesions (see discussion). The reference does establish that it was known in the art at the time the invention was made to use the sensitive PCR technique to detect papillomavirus in samples.

Androphy (Ciba Found. Symposium, 1986) teaches the use of interferon for the treatment of papillomavirus. Treatment may be giving intralesionally or systemically (see abstract). The reference established that is was known in the art at the time the invention was made to treat papillomavirus infection with an antiviral agent.

Gross G (Intervirology) teaches that interferon and other immunotherapies can be used to treat papillomavirus infection. The interferon may be administered systemically or topically or intralesionally (see page 370 column 1). The reference established that is was known in the art at the time the invention was made to treat papillomavirus infection with an antiviral agent.

The prior art establishes that it was known to introduce/extract washing fluids using a microcatheter. The prior art established that it was known to introduce therapeutic agents into the breast duct directly. It was also known in the prior art that papillomavirus lesion were found in the breast duct. Based on what was known in the prior art at the time the invention was made it would have been obvious to one of ordinary skill in the art to (1) utilize a duct washing system for the diagnosis of the presence of a viral agent in the breast duct and (2) utilize a duct washing system for the diagnosis of the presence of a viral agent followed by the introduction of an antiviral agent to the patient. One having ordinary skill in the art would have been motivated to use the cellular and non cellular material extracted by the microcatheter as taught by Evron et al. in conjunction with assays for the presence of papillomavirus in the breast duct. Makita et al., King et al. and Noguchi et al. each establish that the presence of papillomavirus in the epithelial

layers of the breast duct was known in the art. Optimizing the diagnostic condition with repeated sample analysis would be an obvious step to the ordinary artisan. If the timing of the monitoring step provides an unexpected result, Applicant needs to point out what the unexpected results are. Applying a therapeutic antiviral agent to the breast duct would be obvious. Sukumar et al. teach the introduction of a composition into the breast duct, which destroys the epithelial tissue a primary site for papillomavirus infection. Androphy and Gross teache the use of interferon for the treatment of papillomavirus, the interferon can be administered directly to the papillomavirus lesion or it can be administered systemically. Optimizing the treatment condition would be an obvious step to the ordinary artisan.

Therefore, taken what was known in the prior art as a whole it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to identify the presence of papillomavirus in a single breast duct and apply treatment to the single breast duct.

Conclusion

No claims allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/28/04